REMARKS

I. Status of the claims

After the entry of this amendment claims 1-8, 13-15, 20, 21, and 24-36 will be pending in this application. Claims 9, 10, 16, and 17 had been cancelled prior to this amendment. Claims 11, 12, 18, 19, 22, and 23 have been cancelled in this amendment in order to expedite the grant of a patent with the allowed claims. Applicants reserve the right to pursue protection for all cancelled subject matter in future divisional applications. Claims 24-26 have been amended to place them in independent form, or to depend only from claims 1 and 5, as suggested by the Examiner. No other claim has been amended. Applicants acknowledge the allowance of claims 1-8, 13-15, 20, and 21.

New claims 27-36 have been added. The new claims depend from claim 1 and consequently their examination would not require a new search. These claims find full support in previously presented claims and the specification and, therefore, do not constitute new matter. In particular support for new claim 27 is found in pending claim 4, and in the specification at p. 13, lines 8-9. Support for new claim 28 is found in pending claim 4. Support for new claims 29-32 is found in pending claim 4, and in the specification at p. 7, lines 20-26. Support for new claim 33 is found in the specification at p. 7, line 27, where 4-hydroxycyclohexyl has been disclosed as an example of substituted cycloalkyl. Support for new claim 34 is found in pending claim 1. Support for new claim 35 is found in pending claim 1 and in the compounds of examples 24, 25, 70, 77, 116, 117, 124, 125, 126, 127, 128, 130, 131, 132, 133, 134, 135, 139, and 140. New claim 36 is a subset of claim 35.

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II. Information Disclosure Statement

As suggested by the Examiner, Applicants are filing an Information Disclosure Statement (IDS) concurrently with this Response and Amendment. This IDS lists the abstracts the Examiner did not initial from the IDS filed on February 13, 2001.

III. Allowance of claims 1-8, 13-15, 20, and 21

Applicants acknowledge the allowance of claims 1-8, 13-15, 20, and 21. The Examiner indicates that the proviso at the end of claim 1 suggested the presence of close prior art. However, Applicants have already responded to the Examiner's rejections in this regard. See, *e.g.*, the Response and Amendment filed on January 16, 2002.

IV. Rejection of claims 24-26

The Examiner rejected claims 24-26 apparently for depending from withdrawn claims or for including non-elected uses. Applicants rewrote claims 24-26 to recite the treatment of angina pectoris. These amendments should place claims 24-26 in condition for allowance.

V. Claims withdrawn under 37 C.F.R. § 1.475

The Examiner withdrew claims 11, 12, 18, 19, 22, and 23 allegedly for being directed to more than one utility. Applicants respectfully traverse for the reasons of

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record. However, in order to expedite prosecution, claims 11, 12, 18, 19, 22, and 23 have been cancelled.

In order to avoid any conclusion of acquiescence with respect to the Examiner's comments regarding the patentability of claims 11, 12, 18, 19, 22, and 23, Applicants provide the following remarks. The Examiner indicates that claims 11, 12, 18, 19, 22-23 are "not believable on their face; [have] no established regimen of treatment, [and require] undue experimentation to find out what host-dosage relationship would produce what result." Applicants respectfully disagree.

The Examiner has not provided any supporting arguments or references as to why these claims are not believable. Therefore, the Examiner has not met his burden under current law of proving a prima facie case of non-enablement. *In re Budnick*, 537 F.2d 535, 537, 190 USPQ 422, 423 (C.C.P.A. 1976).

Moreover, because the determination of appropriate dosage depends on the particular characteristics of the individual to be treated (specification at p. 19, lines 1-9), such determination is done routinely by practitioners upon examination of a patient. The courts have recognized that such practice would not be considered undue experimentation when the process is merely routine and sufficient guidance is provided in the specification. M.P.E.P. § 2164.01; 2164.01(a); *In re Wands*, 858 F.2d 731, 737; 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (indicating that "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.") Applicants direct the Examiner's attention to page 19, lines 1-18 of the specification, where appropriate dosage ranges for the compounds

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of the invention are discussed. Therefore, the determination of suitable dosages is not considered undue experimentation.

As mentioned earlier, Applicants reserve the right to pursue protection for all cancelled subject matter in future divisional applications.

Conclusions

In view of the foregoing amendments and remarks, Applicants respectfully request the examination of this application and the timely allowance of the pending claims.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: February 9, 2004

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